K072094

SEP 2 5 2008

Pg 1 of 2

510(K) Summary

M. I. Tech Co., Ltd.
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Date Prepared: July 7, 2007

Contact: Aeyoung Heo, Regulatory Affairs Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: CHOOSTENT™ covered Esophageal Stent
   Classification Name: Prosthesis, esophageal
   Product Code ESW
   Common/Usual Name: Esophageal Stent

2. **Equivalent legally marketed devices:** Ultraflex™ Esophageal Stent System (K012883, Boston scientific corporation)

3. **Indications for Use (intended use)** The CHOOSTENT™ covered esophageal stent is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and or extrinsic malignant tumors only and occlusion of concurrent esophageal fistula.

4. **Description of the Device:**. This stent is a self-expanding tubular prosthesis designed to maintain patency of esophageal stricture caused by malignant tumors. The unique structure of the membrane connects the several separated segments to increase the flexibility of the stent and to prevent migration and tumor in-growth. Since the both ends of stent have larger bands, the stent can be fixed firmly within the esophagus. There are totally 12 excellent radiopaque markers made of gold wires; 4 each on both ends of the stents and another 4 at the center. Two retrieval lassos attached to the both ends play a role in removing the stent when necessary or pulling the stent up to the right position in case the stent has been deployed deeply down the stricture. The fully expanded diameter is 18mm for the body and 24mm for both larger bands. There are four standard lengths: 80mm, 110mm, 140mm, 170mm.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and test laboratory testing indicates that the new device is as safe and effective as the predicate devices.

K072094
pg 2 of 2

6. Substantial Equivalence Chart

Manufacturer	Boston Scientific	M. I. Tech Co., Ltd.
Product Name	Ultraflex™	CHOOSTENT™
510(k)	K012883	--
Indication for use	The proposed Ultraflex Esophageal Stent System is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.	The CHOOSTENT™ covered esophageal stent is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and or extrinsic malignant tumors only and occlusion of concurrent esophageal fistula.
Specification comparison		
Deployment time	21 Sec	11-17 Sec
Expansion force	0.81 lb.	0.83 lb.
Compression force	2 lb	2 lb
Dimension: diameter	18 mm	18 mm
Corrosion (in simulated gastric fluid)	No corrosion after 90 days	SAME
Tensile strength	>90 lb (more than adequate for safe removal)	>15 lb. (more than adequate for safe removal)
Construction materials	Nitinol wire and Polyurethane	Nitinol wire, gold, and Nusil silicone

7. Conclusion After analyzing both bench as well as laboratory testing to applicable standards, it is the conclusion of M. I. Tech Co., Ltd. that the CHOOSTENT™ covered Esophageal Stent is as safe and effective as the predicate devices, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2008

M.I. Tech Co., Ltd.
c/o Daniel Kamm. P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K072094
Trade/Device Name: CHOOSTENT.™ covered Esophageal Stent
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: July 11, 2008
Received: July 21, 2008

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K072094

Indications for Use

510(k) Number (if known): K072094

Device Name: CHOOSTENT™ covered Esophageal Stent

Indications For Use:

The CHOOSTENT™ covered esophageal stent is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and or extrinsic malignant tumors only and occlusion of concurrent esophageal fistula.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072094